DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

Form Approved: OMB No. 0910-0025. Expiration Date: October 31, 1991. See Page 4 for OMB Statement.

DOCKET NUMBER

N	OTE: No laser light show, projection system, or device m application in accordance with 21 CFR 1010.4.	nay vary from comp	liance with 21 CFR 1040	0.11(c) in design or u	use without the approval of this		
1.	Check all applicable boxes and type or print the requested information.	INSTRU	CTIONS 2 2 2 iil your application to the d Drug Administration,	00 FEB 25 P ne Dockets Manage Room 4-62, 5600 Fi	ment Branch (HFA-305), Food shers Lane, Rockville, MD 20857.		
_	Submit an original and four (4) copies.	4. En	ter docket number if as	signed.			
	Preston Productions Inc.						
2.	ADDRESS OF COMPANY (Include ZIP CODE) (If P.O. Box	is used, include act	ual street address also.)	The second secon		
	160 Locke Drive, Marlborough, MA 0175	2					
3.	NAME AND TITLE OF RESPONSIBLE PERSON		. (Include area code)		5. DATE OF SUBMISSION		
	Charles Singer, Vice President	(508) 624-4	1100 ext. 521		February 9, 2000		
6.	6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OFYEARS FROM THE DATE OF ISSUE. (In general, the Agency will approve a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)						
7		PRODUCT DESCRI	PTION AND USE				
a.	LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASE	R LIGHT SHOW(S) A	ND PROJECTOR(S)				
	Please see attached document						
	PRODUCT FOR WHICH A VARIANCE IS REQUESTED ☐ A laser display device ☐ A projector for a laser light show ☐ A laser light show ☐ Other (Specify) Variety of Class IIIb & IV L	aser Shows	f. PRODUCT IS INTEND More than 15 More than 5 to Less than 5 da g. TOUR IS INTENDED More than 6 r	days out not more than 1 sys TO RUN FOR			
c.	 Projectors are intended for sale, lease, or loan to other laser light show producers 		☐ 1-6 months ☐ Less than one	month			
	PRODUCT IS INTENDED FOR USE IN A Planetarium or other dome projection structure Theater Hotel/motel ballroom or meeting room Store displays Trade show or convention Discotheque or night club Pavilion Indoor arena Outdoor arena Museum Outdoor unenclosed area Other (Specify) PRODUCT IS INTENDED TO BE USED At only one (Fixed) location At a variety of (Tour) locations Other (Specify)		 Not applicable (Not a tour) Other (Specify) h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS ☒ Frontscreen projections ☒ Rear screen projections ☒ Holographic displays ☒ Multiple reflection/diffraction effects ☒ Audience scanning (Also includes scanning any accessible uncontrolled areas) ☒ Reflections from stationary mirrors or mirrored surfaces (Beam Matrices) ☒ Stationary irradiation of rotating mirror balls, etc. ☒ Scanning irradiation of rotating mirror balls, etc. ☒ Fiber optic projections ☒ Fog, smoke, or other scattering enhancement effects ☐ Other (Specify) 				
8		LASER RADIA	TION LEVELS				
H	LASER MEDIUM (Ar, He-Ne, etc.)	WAVE LENG		PFA	IK POWER (watts)		
Η.		TIATECENO		,			
Ľ	Please see attached document				····		
L							
9.	9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE						
	Please see attached document						
10	D. REASON FOR REQUESTING VARIANCE				remajoran en		
	☐ Compliance with the limits of 21 CFR 1040:11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible						
1	Other or additional explanation (Specify)						
١	00V-0791				VAR1		

				The same of the sa	A CONTRACTOR OF THE STATE OF TH
11.	MAN	NNER IN WHICH IT IS PROPO	SED TO DEVIATE FROM T	HE REQUIREMENTS OF THE APPLICAB	LE STANDARD
	X	It is proposed to deviate fr accessible emission limits s	om the provisions of 21 Cl pecified in 21 CFR 1040.1	FR 1040.11(c) in that the accessible en 1(c).	rission level would exceed the
] It is proposed to deviate fr			
12.	ADV	ANTAGES TO BE DERIVED F	ROM SUCH DEVIATION		
	(3)	Laser light shows and disployed the limits imposed by 2	lays are accepted popular 1 CFR 1040.11(c) is necess	media in entertainment and the arts ary to achieve the required effects in t	Use of power levels in excess these media.
] Other or additional advan	tages (describe and expla	in).	
					·
13.	EXPL	LAIN THE ALTERNATE MEAT es not checked, using addition	NS OF RADIATION PROTECTION STATES IN A SHEETS AS NECESSARY.	CTION TO BE PROVIDED. (Check as mo State any other means of radiation pr	any boxes as apply. In Item 14 "Remarks," justify any otection that will be used.)
	a. 🔀	All laser products, systems be reported as required by accomplished prior to any	/ 21 CFR 1002.10 and 100	2.12 using the reporting guides provide	1040.10 and the conditions of this variance and will led for such purpose. These actions will be
	b. 🔀	Effects not specifically ind the variance has been obt	icated in this variance app ained and the required re	plication will not be performed. No of eports or supplements, as applicable, b	ther effects will be added until an amendment to nave been submitted.
		areas will not be permitte screens.	d except for diffuse reflec	ctions produced by the atmosphere, a) into audience or other accessible uncontrolled dded atmospheric scattering media, and target
	d. 🔀	where such persons are of	ermitted to be. Operators	I will not be permitted at any point le byees are permitted to stand or 2.5 m s, performers, and employees will not e limits specified in 21 CFR 1040.11(c).	ss than 3.0 meters above any surface upon which eters below or in lateral separation from any place be required or allowed to view radiation above the
	e. 🛚	Any product which relies of directly senses scanner mo	on scanning to meet accessorion and which will react	ss, exposure, or product class limits will fast enough to preclude exceeding th	l incorporate a scanning safeguard system which ne applicable limit.
	f. 🛚	All laser light shows shall l	be under the direct and po	ersonal control of trained, competent	operator(s). The operator(s) will:
		(1) Immediately terminat	e the emission of light sho	ow radiation in the event of any unsaf	e condition;
		(2) Be located where all b	eam paths can be directly	observed at all times; and	
		(3) Be an employee of the	variance holder who wil	I be responsible for the training and the	ne conduct of the operator.
	g. 🛚	The maximum laser proje	ctor output power will no	t exceed the level required to obtain	the intended effects.
	h. <table-cell></table-cell>	The projection system (i.e immobilized to prevent u prevent overfilling of screen.)	nintended movement or i	misalignment. Beam masking will be	ighting effects) will be securely mounted or provided as an inherent part of the system design to
	i. 🛭	Laser projectors will not b demonstrates that they h projector(s)	e delivered to any other pave a variance in effect at	party under an agreement of sale, lea t the time of delivery that permits the	se, or loan unless and until the recipient m to produce laser light shows incorporating such
	j. 128	lease or horrow the equi	pment, adequate users' in ent light show manufactu	nstructions for safe installation and op rer to submit the required reports and	ors/systems will provide to parties who purchase, leration which explain the responsibility of the dapply for and obtain a variance from CDRH prior to
	k. (<u>S</u>	and performance of each variance, and the control (American National Standapplicable, state or local 1040.11(c) will be clearly switches, photo cells, barand to final or permanen CFR 1002.31. A copy of the	show. These procedures of access to radiation are dards Institute, 1430 Broadequirements. Laser radia identified by the posting riers, guards, etc.). These tareas. The variance hold be variance application.	will be in sufficient detail to ensure co as using the procedures described in the dway, New York, NY 10018) or any ot ation areas which can contain radiation of warning signs and/or restricting acc requirements apply to temporary are der will retain the records of these pro- the approval letter, current procedures	of written procedures for setup, alignment, testing, ompliance with 21 CFR 1040.10, the conditions of this he ANSI Z136.1 standard for the safe use of lasers her equivalent user consensus standard and, where in levels above the limits specified in 21 CFR tess through physical means (such as pressure as (such as during set up and alignment procedures) occdures and the results of all tests as required by 21 s, and records relating to each particular show will be son by FDA and other responsible authorities.

- Advance written notification will be made as early as possible to appropriate federal, state, and locations clearly and completely identified, and a basic description of the proposed effects including a statement of the maximum power output intended. Such notifications will be made, but not necessarily be limited, to:
 - (1) The Center for Devices and Radiological Health, Office of Compliance and Surveillance (HFZ-312), 1390 Piccard Drive, Rockville, MD 20850, providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and accession numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance.
 - (2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time (i.e., including set up, alignment, rehearsals, performances, etc.). If the FAA objects to any laser effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the objectionable effects will be deleted from the show.
 - (3) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be resolved or the effects deleted. (A list of federal and state offices is available from the Center for Devices and Radiological Health upon request.)

1	4	R	F	M	Δ	R	ĸ۶	

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading, or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE

Charles Sign

16. NAME (Type or Print)

17. TITLE

Charles Singer

Vice President, Production Services

Attachments to Application for a Laser Light Show Variance Submitted by Preston Productions Inc.

Attachment to # 7a; List Name and/or Model Numbers of Laser Light Projectors

Preston Productions Inc. will primarily use Model Series 300 laser projectors manufactured by Image Engineering Corp. Preston Productions Inc. will also be renting and/or purchasing various lasers & laser projectors from a wide variety of vendors on an "as needed" basis. Below is a list of additional vendors and the laser product model series that are rental candidates.

Name of manufacturer

Name and/or model of laser projector

Holo-Spectra Inc.

SpectraScan Series SpectraBeam Series LitePipe Series

LaserAnimation Sollinger GmbH

Accurate Laser Projector

Laser Media Inc.

LM Series Sting Ray

Laserpromotions

Optical Module Series

Laser Systems Design Inc.

Excalibur Series Cascade Series Microscan Series

Lowell Products Development Inc.

Nova Series Horizon Series Q - Beam Series

MediaLas Laserproducts GmbH

Catweasel Series

Mobolazer Inc.

ML Series

Attachment to # 7a; List Name of Laser Light Shows

Preston Productions Inc. will be producing a wide variety of Class IIIb & Class IV laser shows at various locations for varying durations. Preston Productions Inc. initial show is titled:

Laser Show at Massachusetts Bay Community College

Attachment to #8; Laser Radiation Levels

Laser medium	Wavelength	Power	Details
Semi-Conductor	450 nm to 690 nm	100 mW	Continuous wave
Helium-Neon	540 nm to 640 nm	100 mW	Continuous wave
Nd:YAG	450 nm to 680 nm	100 Watts	CW & Pulsed - Average power
Nd:YVO ₄	450 nm to 680 nm	100 Watts	CW & Pulsed - Average power
Argon	450 nm to 530 nm	60 Watts	Continuous wave
Krypton	440 nm to 680 nm	20 Watts	Continuous wave
Mixed, Ar & Kr	450 nm to 680 nm	60 Watts	Continuous wave

Attachment to #9; Pulse Duration & Rate, Scanning Frequency & Amplitude

Scan rate: variable, 0 Hz (static) to 1 kHz

Scan angle: variable, 0° to 90° (optical)

Angular deflection rate: variable, 0° per second to 50,000° per second

Modulation rate: variable, 0 to 5 MHz
Amplitude modulation: variable, 0 to 100%
Modulation duty cycle: variable, 0 to 100%

R ions Inc.

ichusetts 01752



7099 3400 0005 4225 9447





FAID FRAMINGHAM, MA 01701 FEB 19, 00 AMOUNT

\$3.86

To:
Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, MD 20857

HIST CLASS
LETUCH RECEIPT
REQUESTED